CV
15V

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

(1) MICHAEL TAYLOR, an individual)
)
Plaintiff,)
)
v.)
)
(1) THE APOTHECARY SHOPPE, LLC, a Delaware limited liability company,)
)
Defendant.)

Case No.: 14 CV -063 TCK - TLW

COMPLAINT

Plaintiff Michael Taylor, by and through his attorneys, alleges as follows:

NATURE OF THE ACTION

1. Plaintiff Michael A. Taylor is an inmate held by the Department of Corrections of the State of Missouri ("DOC") and sentenced to death. His execution by lethal injection is currently scheduled for February 26, 2014. Defendant The Apothecary Shoppe, LLC is a compounding pharmacy located in Tulsa, Oklahoma. Defendant has contracted with DOC to produce and provide compounded pentobarbital as the lethal ingredient in the lethal injection that will be used to execute Mr. Taylor.

2. Defendant is not registered with the Food & Drug Administration ("FDA") as a drug manufacturer. Defendant violates federal law when it delivers to DOC, for introduction into interstate commerce, a copy of a commercially available pharmaceutical product.

3. The use of pentobarbital produced by this pharmacy is substantially likely to cause Mr. Taylor severe, unnecessary, lingering, and ultimately inhumane pain for a number of reasons. First, it is unclear what ingredients Defendant uses to create the pentobarbital

compound it intends to sell to the DOC. Second, Defendant obtains the active ingredients used in the compound from unknown sources and thus there is no way to verify whether these sources are regulated and approved by the FDA or what standards they use when developing their products. Third, given the lack of regulation governing Defendant's compounding practices, there are no assurances that Defendant has compounded the pentobarbital it will provide to DOC in a sterile environment. Fourth, there is no evidence that Defendant will or even has the capacity to test the pentobarbital it will provide for the execution of Mr. Taylor to ensure it will not cause unnecessary pain and suffering.

4. As a result, the pentobarbital compounded by this substantially unregulated pharmacy is of unreliable sterility, identity, purity, potency and efficacy.

5. Further, Defendant has provided DOC with dangerously inaccurate information regarding the proper storage of pentobarbital. If DOC heeds Defendant's guidance and stores the pentobarbital as Defendant suggests, there is a grave risk that Mr. Taylor will suffer severe pain or an immediate, severe allergic reaction if injected with Defendant's pentobarbital compound.

6. There is an additional risk that the compounded pentobarbital will be sub-potent, meaning that Mr. Taylor could experience severe pain and suffering or a severe allergic reaction prior to losing consciousness and continuing throughout an unnecessarily long and inhumane execution.

7. Several recent incidents demonstrate that use of compounded pentobarbital in Mr. Taylor's execution creates a very real and substantial risk that he will suffer severe, unnecessary, lingering, and ultimately inhumane pain. On January 10, 2014, an Oklahoma inmate executed by a protocol using compounded pentobarbital cried out within twenty seconds of receiving the injection that he felt his whole body burning, a sensation consistent with receipt of contaminated

pentobarbital. On October 15, 2012, a South Dakota inmate was executed by use of compounded pentobarbital. After injection of the drug, the inmate cleared his throat, gasped heavily, and snored; his skin turned a blue-purplish hue over a ten-minute period; his heart continued to beat ten minutes after he stopped breathing; and it took twenty minutes for the state to declare him dead. These events are consistent with receipt of a contaminated or sub-potent compounded drug.

8. In addition, in 2012, the nation faced a public health disaster when a nation-wide epidemic of fungal meningitis resulted in 64 deaths and over 700 infections resulting from contaminated injections produced by a compounding center in Massachusetts.

9. By this action, Plaintiff seeks to recover damages from, a declaratory judgment against, and an injunction restraining Defendant from effectuating the illegal delivery of this unidentified, unregulated, untested, and unsafe pharmaceutical product Defendant claims is compounded pentobarbital to the DOC for use in his execution.

JURISDICTION AND VENUE

10. This action arises under the Constitution of the United States, the Eighth and Fourteenth Amendments thereto, and the laws of the United States, including 42 U.S.C. § 1983 and 28 U.S.C. §§ 2201 and 2202, as well as under Oklahoma law.

11. This Court has jurisdiction to hear claims of this nature pursuant to 28 U.S.C. §§ 1331–1332, and 1367.

12. The amount in controversy in this action exceeds $75,000.

13. This Court has personal jurisdiction over Defendant because Defendant's principal place of business is in Tulsa, Oklahoma, and because Defendant's wrongful conduct takes place, and will continue to take place, in Oklahoma.

14. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391, because the events giving rise to Plaintiff's claims have occurred, and will occur, in this District.

PARTIES

15. Plaintiff Michael Taylor is a United States citizen, and has been, at all times relevant hereto, a resident of Jackson County, Missouri. Mr. Taylor was sentenced to death on June 17, 1994. Plaintiff has resided in the Missouri Department of Corrections system since that time.

16. Defendant, The Apothecary Shoppe, LLC, a Delaware limited liability company, is a "compounding pharmacy" with its principal place of business in Oklahoma. Upon information and belief, the members of Defendant, The Apothecary Shoppe, LLC, are citizens of Oklahoma.

(a) Defendant is licensed as a compounding pharmacy in the state of Oklahoma.

(b) Defendant received a license as a compounding pharmacy in the state of Missouri on Monday, February 3, 2013—i.e., within the past week.

(c) Upon information and belief, Defendant has, pursuant to a contract with the Department of Corrections of the State of Missouri ("DOC"), provided DOC with syringes of compounded pentobarbital solution, a barbiturate drug, which DOC has used to carry out several recent executions. Upon information and belief, pursuant to DOC's execution protocol, Defendant is a member of the DOC "execution team," and will continue to provide compounded pentobarbital for executions carried out by lethal injection in Missouri. *See, e.g.*, Jason Hancock, *Execution Secrecy Draws Criticism in Missouri*, Kansas City Star, Feb. 7, 2014; *Oklahoma Pharmacy Tied to Execution Seeks Mo. Permit*, Associated Press, Feb. 3, 2014,

http://www.bnd.com/2014/02/03/3037787/oklahoma-pharmacy-seeks-missouri.html.; Chris McDaniel, *After Supplying for Three Missouri Executions, Pharmacy Plans To Register in State*, St. Louis Public Radio, Feb. 2, 2014, http://news.stlpublicradio.org/post/after-supplying-three-missouri-executions-pharmacy-plans-register-state.

(d) Pursuant to its execution protocol, DOC pays approximately $8000 in cash to Defendant for compounded pentobarbital for each execution. Deposition of Dave Dormire (January 15, 2014), 127:23-128:8, attached as Ex. 1 ("Dormire Tr.").[1]

FACTUAL ALLEGATIONS

I. Defendant The Apothecary Shoppe knowingly compounds and provides pharmacy-compounded pentobarbital to DOC for use as the lethal chemical in executions and will do so for the execution of Michael Taylor scheduled for February 26, 2014.

17. DOC has contracted with Defendant to produce and provide pharmacy-compounded pentobarbital for use in the execution of inmates. Upon information and belief, this contract includes producing and providing compounded pentobarbital for the execution of Mr. Taylor, currently scheduled for February 26, 2014.

18. Upon information and belief, Defendant has prepared and supplied drugs used in at least three previous executions by the DOC, and intends to do the same for the execution of Mr. Taylor.

19. Upon information and belief, Defendant is the only compounding pharmacy under contract with the DOC for the provision of pharmacy-compounded pentobarbital. Dormire Tr. 56:8-16.

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[1]David Dormire is the Director of the Division of Adult Institutions of the DOC. His deposition was taken on January 15, 2014 in the matter captioned *David Zink, et al. v. George A. Lombardi, et al.*, No. 12-CV-4209, before the District Court for the Western District of Missouri.

20. Defendant is aware that the compounded pentobarbital it prepares and supplies to the DOC is to be used for the execution of individuals on death row in the State of Missouri.

21. Defendant intends to prepare compounded pentobarbital to be used in Mr. Taylor's execution in a manner that is inconsistent with state and federal law and fails to ensure that the compounded pentobarbital is safe, unadulterated, and effective.

22. Defendant is located and has its principal place of business in the State of Oklahoma.

II. According to DOC's current execution protocol—adopted as a last resort due to the unavailability of other drugs—DOC uses compounded pentobarbital as the lethal ingredient in lethal injections, and the compounding pharmacy is a member of the state execution team, entitled to state privileges, including confidentiality.

a. Since 2010, DOC has followed three different execution protocols, changing from drug to drug based on market availability rather than medical considerations such as efficacy and potency.

23. Missouri law provides that the Director of DOC should select a lethal-injection protocol to govern executions by lethal injection. The Director is authorized to select an "execution team" consisting of "persons who administer . . . lethal chemicals" as well as "persons, such as medical personnel, who provide direct support for the administration of . . . lethal chemicals." Mo. Rev. Stat. § 546.720(2).

24. In 2010, DOC's execution protocol provided for the administration of three drugs: sodium thiopental, pancuronium bromide, and potassium chloride. *See In re Lombardi*, No. 13-3699 --- F.3d ---, 2014 WL 288937, at *1 (8th Cir. Jan. 24, 2014). DOC's supply of sodium thiopental had depleted by March 1, 2011, and Missouri was unable to obtain more of the drug because, among other things, the European Union adopted regulations limiting exports of sodium thiopental to countries that apply the death penalty. *See id.*

25. In May 2012, the Director of DOC issued a new execution protocol adopting propofol as the lethal ingredient to be used in lethal injections. Although propofol is the leading anesthetic used in hospitals and clinics in the United States, nearly 90 percent of the U.S. supply of propofol is produced in the European Union. In 2013, the E.U. threatened to limit propofol exports to the United States if its use in lethal injection executions continued. In response to these threats, DOC abandoned the propofol protocol as of October 18, 2013, before using it in a single execution, and issued a new protocol adopting pentobarbital as the lethal ingredient. Upon information and belief, the pentobarbital protocol is still valid and governs executions carried out by DOC.

26. Until in or about January 2012, the Danish company Lundbeck manufactured and marketed the only available pentobarbital, under the trade name Nembutal, in the United States. In or about January 2012, Lundbeck sold the exclusive rights to pentobarbital to an American company, Akorn, Inc. Per the conditions of the sale, Akorn is prohibited from selling pentobarbital for use in lethal injection executions.

27. Because DOC is unable to acquire actual pentobarbital, i.e., Nembutal, for use in executions, DOC has contracted to purchase compounded pentobarbital for use in its lethal injection executions.

b. The Missouri DOC has designated a compounding pharmacy as a member of the state execution team and afforded the pharmacy corresponding privileges, generally applicable only to state actors.

28. The current DOC execution protocol includes a compounding pharmacy as a member of the execution team. The protocol defines "execution team" as follows:

> The execution team consists of department employees and contracted medical personnel including a physician, nurse, and pharmacist. The execution team also consists of anyone selected by the department director who provides direct support for the

> administration of lethal chemicals, including individuals who prescribe, ***compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure***.

29. The Missouri statute on methods of execution provides that "[t]he director of the department of corrections shall select an execution team which shall consist of those persons who administer lethal gas or lethal chemicals and those persons, such as medical personnel, who provide direct support for the administration of lethal gas or lethal chemicals." Mo. Rev. Stat. § 546.720(2).

30. DOC has asserted that the compounding pharmacy providing pentobarbital is a member of the state's execution team.

31. Upon information and belief, Defendant is the compounding pharmacy that DOC has identified as part of the execution team. *See, e.g.*, Jason Hancock, *Execution Secrecy Draws Criticism in Missouri*, Kansas City Star, Feb. 7, 2014; *Oklahoma Pharmacy Tied to Execution Seeks Mo. Permit*, Associated Press, Feb. 3, 2014, http://www.bnd.com/2014/02/03/3037787/oklahoma-pharmacy-seeks-missouri.html; Chris McDaniel, *After Supplying for Three Missouri Executions, Pharmacy Plans To Register in State*, St. Louis Public Radio, Feb. 2, 2014, http://news.stlpublicradio.org/post/after-supplying-three-missouri-executions-pharmacy-plans-register-state.

32. Missouri law provides that "[t]he identities of members of the execution team, as defined in the execution protocol of the department of corrections, shall be kept confidential." Mo. Rev. Stat. § 546.720(2).

33. The DOC and its employees have refused to reveal the identity of the pharmacy that compounds pentobarbital on the ground that it is a member of the execution team, whose identity is protected by Missouri Revised Statuted § 546.720.2. *See* Dormire Tr. 45:4-9; 61:25-62:2; 64:13-23; 65:3-5; 93:8-10; 122:11-15; 142:15-16; 147:10-15.

34. The DOC's relationship with Defendant extends beyond that of a traditional private purchaser of pharmaceutical drugs from a compounding pharmacy. *See In re Lombardi*, 2014 WL 288937, at *2 (discussing Missouri DOC's adding a compounding pharmacy to its execution team on October 18, 2013). Rather, as a member of the execution team for the state, Defendant has received privileges reserved for state actors engaged in executions in Missouri. *See id.* at *5 (discussing the privileges that attach to the compounding pharmacy by virtue of its membership on the execution team under Missouri law).

35. For these reasons, Defendant has acted and continues to act under the color of state law when it produces and provides compounded pentobarbital to DOC for use in executions.

III. The pentobarbital Defendant will provide to the State of Missouri for use as the lethal chemical in Mr. Taylor's execution will cause significant, unnecessary, and lingering pain and suffering.

a. Defendant's compounding of pentobarbital for DOC is substantially unregulated by federal law and violates Oklahoma law.

36. Traditional compounding by pharmacies uses active and inactive ingredients to meet the needs of patients whose needs cannot be met with FDA-approved products. *See* Declaration of Larry D. Sasich (Feb. 11, 2014) ("Sasich Decl.") ¶ 6 (Ex. 2). The Food & Drug Administration ("FDA") generally exercises enforcement discretion over traditional pharmacy compounding. *Id.*[2]

37. Defendant's use of raw ingredients to manufacture a copy or substitute of a drug approved by the FDA for general distribution rather than to meet the unique needs of a specific

[2]Dr. Larry D. Sasich, PharmD, MPH, FASHP, is a consultant specializing in drug safety and efficacy issues. He has written numerous publications on subjects relevant to this Action. He consulted with Plaintiff and counsel in the matter captioned *David Zink, et al. v. George A. Lombardi, et al.*, No. 12-CV-4209; he has also consulted with counsel with respect to this Action.

patient is a form of non-traditional compounding that is not regulated by the FDA or federal law. Non-traditional compounding is therefore regulated, if at all, only by the states. *See id.* ¶ 7.

38. Defendant's compounding of pentobarbital that it then sells to the DOC for use in executions falls outside permissible "compounding" as defined and regulated by Oklahoma law. Okla. Stat. tit. 59, § 353.1(6)(b).

39. Oklahoma law forbids the compounding of a drug that is "commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug," unless "patient therapy is compromised." Okla. Stat. tit. 59, § 535:15-10-8(h).

40. Defendant violates Okla. Stat. tit. 59, § 535:15-10-8(h), by issuing compounded "pentobarbital" to DOC because the compounded drug "is essentially a copy of an available FDA-approved drug," and also because the FDA-approved drug, Nembutal, pentobarbital's trade name, is "commercially available in the marketplace."

41. Oklahoma state law does not require compliance with the less stringent United States Pharmacopeia Chapter 797 standards for producing sterile drugs. The Oklahoma State Board of Pharmacy, however, does require compliance with USP Chapter 797. *See* Sasich Decl. ¶ 5.

42. "[T]he potential for product contamination in compounded drugs is far higher than in manufactured drugs" due to the lack of regulation. *Id.* ¶ 13.

b. Drugs from compounding pharmacies such as The Apothecary Shoppe are unreliable as to their identity, purity, potency, and efficacy.

43. Compounding pharmacies such as Defendant fabricate pharmaceutical products from "Active Pharmaceutical Ingredients" or APIs. Sasich Affidavit, ¶¶ 12, 16-25.

44. "Ethical chemical manufacturers . . . are unlikely to sell chemicals that may be used in grey market drug production operations . . . ." *Id.* ¶ 18. As a result, compounding

pharmacies like Defendant that compound products that are copies of commercially available drugs are likely to obtain their APIs from India or China or other sources not registered with or inspected by the FDA. *Id.* ¶ 17-18. In contrast, FDA-compliance requires active ingredients to be manufactured in an FDA-approved plant by a manufacturer that holds a Drug Master File for the chemical. *Id* ¶ 17.

45. "Chemicals used in compounding are highly suspect, and there is no practical way to verify their quality, constitution or uniformity in limited pharmacy settings." *Id.* ¶ 18.

46. In this unregulated market, a chemical labeled to represent a certain active ingredient may actually contain another, quite different ingredient. Practitioners, regulators, and experts have identified this problem in chemicals distributed in large quantities to pharmacies throughout the nation for use in compounding. *Id.* ¶ 19.

47. Compounding pharmacies typically lack the ability to test chemicals for identity, potency, purity and contamination. Defendant is unlikely to have the capacity to conduct testing to confirm the identities of raw API chemicals used to compound the pharmaceutical product it provides to DOC or to identify the presence of harmful contaminants that pose an immediate safety threat if administered intravenously. *Id.* ¶ 21.

48. In addition, compounding pharmacies typically lack the ability to trace the raw chemicals used in compounding to the original manufacturers for important information regarding the quality, packaging, storage, shipment conditions, and chains of custody of the precursor chemicals. *Id.* ¶ 16.

49. Upon information and belief, Defendant purchases chemicals from a manufacturer that is not registered with, or inspected by, the FDA, and/or purchases chemicals from a

manufacturer without consideration of whether the manufacturer is registered with, or inspected by, the FDA. *Id.* ¶¶ 14-19.

50. Upon information and belief, Defendant does not compound pentobarbital in voluntary compliance with the FDA's Good Manufacturing Practices.

51. Due to the questionable and unregulated sources of the ingredients and the unregulated and unreliable manufacturing practices used by compounding pharmacies to compound pharmaceutical products, the pentobarbital compounded by Defendant and sold to DOC is likely unreliable in terms of its sterility, identity, purity, potency, and efficacy.

52. In two recent executions, inmates injected with compounded pentobarbital exhibited reactions consistent with receipt of a contaminated or sub-potent drug. In one case, the inmate cried that he felt his whole body burning. *Id.* ¶¶ 60-61. In a second case, the inmate appeared to clear his throat, gasp heavily, and snore, his skin turned a blue-purplish hue over a ten-minute period, he opened his eyes during the execution and they remained open until his death, and his heart continued to beat ten minutes after he stopped breathing. *Id.* ¶¶ 62-63.

53. Compounded drugs generally do not meet federal requirements for purity, potency, efficacy and safety. *Id.* ¶¶ 13, 21, 27.

54. Experts have concluded "that drugs compounded in accordance with USP Chapter 797 have a low standard of sterility assurance compared to the federal standard." Compounding pharmacies generally do not assess the sterility of the compounded pharmaceutical products they produce, nor do they convey it to prescribers or patients. *Id.* ¶ 20.

c. The testing by a laboratory fails to ensure the identity, purity, potency, and efficacy of the pharmaceutical product Defendant supplies DOC.

55. DOC has represented that Analytical Research Laboratories ("ARL") tested at least one previous batch of the product that Defendant represented to be pentobarbital compounded for DOC.

56. After-the-fact testing does not compensate for the absence of reliable, FDA-approved raw materials obtained from reputable suppliers. *Id.* ¶ 33.

57. ARL has represented that it is accredited by the American Association for Laboratory Accreditation ("A2LA"). The probative value of A2LA's accreditation as to analytical testing of compounding-pharmacy products is "unknown." *Id.* ¶ 42.

58. Plaintiff's expert Dr. Sasich, is aware of no governmental entity, federal or state, that recognizes "accreditation" by A2LA. *Id.*

59. In its test of Defendant's pentobarbital compound, ARL's indication of a given concentration level was "not validated." Dr. Sasich notes that this admission "erodes confidence in the reported concentration." *Id.* ¶ 43.

60. "Testing" does not resolve key questions regarding the sterility, identity, purity, potency, and efficacy of the compounded pharmaceutical product Defendant represents is pentobarbital. In particular, the "testing" results do not identify the source of the pentobarbital sodium API; do not state whether the API meets FDA or even USP standards; do not state whether the pentobarbital sodium API was produced in an FDA facility meeting Good Manufacturing Practice Guidelines; and do not indicate whether the compounded drug was produced in a facility that would assure that cross-contamination with drugs that could cause potentially serious allergic reactions would not occur. *Id.* ¶ 44.

61. Further, upon information and belief, neither Defendant nor ARL has tested the pentobarbital compounded by Defendant for adulterants or endotoxins or to assess sterility. *Id.* ¶ 45.

62. Notably, ARL reported favorable test results for the compounding pharmacy that produced the steroids responsible for killing 64 individuals and sickening 686 other individuals in 2012. *See id.* ¶ 38; *see also* Kimberly Kindy, *Labs that test safety of custom-made drugs fall under scrutiny*, Wash. Post, Oct. 5, 2013. ARL is also a party to over 200 lawsuits.

63. Upon information and belief, Defendant has not yet provided the pentobarbital to be used in the execution of Michael Taylor to ARL or any other laboratory for testing. The results of any such testing are therefore unknown.

64. Upon information and belief, Defendant knows, or should know, that the testing of one solution of pentobarbital is not reliable as to the identity, sterility, potency, or efficacy of another solution of pentobarbital. Defendant knows, or should know, that the testing of a sample of one solution of pentobarbital is not tantamount to a warranty as to the identity, sterility, potency or efficacy of the solution as a whole.

d. Defendant has provided DOC with incorrect instructions regarding the storage, care, and use of pharmacy-compounded pentobarbital.

65. Dr. Sasich has explained that the expiration dates required by the FDA on drugs it regulates do not apply to compounded pharmaceutical products – including the compounded-pharmacy product that DOC already used to execute Joseph Franklin on November 20, 2013, Allen Nicklasson on December 11, 2013, and Herbert Smulls on January 29, 2014, as well as the compounded product it intends to use to execute Michael Taylor on February 26, 2014 – because the stability of compounding-pharmacy products is unknown. Sasich Decl. ¶¶ 48, 52-53.

66. Dr. Sasich explained that USP Chapter 797 defines the "Beyond Use Date" (BUD) as the date or time after which a compounded sterile preparation should not be administered, stored or transported. *Id.* ¶ 49.

67. Chapter 797 of the USP assigns BUDs for drugs compounded from non-sterile Active Pharmaceutical Ingredients (High Risk Compounding). USP Chapter 797 classifies compounded pentobarbital sodium as a "high risk" injectable. According to the USP and Dr. Sasich's expert opinion, the BUD for compounded pentobarbital prepared in accordance with USP Chapter 797 is twenty-four hours if it is stored at room temperature, three days if it is refrigerated, and forty-five days if it is frozen. *Id.* ¶¶ 50-51.

68. After the BUD has expired, the compounded pharmaceutical product is not considered safe and effective. *Id.* ¶ 49.

69. Oklahoma regulations require that compounded sterile drug preparations bear a BUD that accords with the requirements of USP Chapter 797. *See* Okla Stat. tit. 59, § 535:15-10-61.

70. Defendant communicated to the Director of the Division of Adult Institutions of the DOC David Dormire that the compounded pentobarbital should be stored at room temperature. Dormire Tr. 105:23-106:4.

71. Dormire testified that the compounding pharmacy had informed another DOC employee that pentobarbital expires thirty days after compounding. Dormire dep. 106:16-107:9.

72. Upon information and belief, the laboratory employed by Defendant to test the compounded pharmaceutical product used to execute Mr. Nicklasson received the product on November 26, 2013, sixteen days before Mr. Nicklasson was executed on December 11, 2013.

73. The laboratory stored the compounded pharmaceutical product later used to execute Mr. Nicklasson at room temperature.

74. Upon information and belief, DOC also stored the compounded pharmaceutical product later used to execute Mr. Nicklasson at room temperature.

75. If the pharmaceutical product used to execute Mr. Nicklasson was compounded sixteen days before the execution, the BUD was exceeded if the drug was stored at room temperature or in a refrigerator. Sasich Decl. ¶ 59. If stored at room temperature or refrigerated, the pentobarbital compounded by Defendant "clearly falls outside the requirements of USP Chapter 797 which states that high risk compounded drugs such as pentobarbital should not be used after one day if stored at room temperature." *Id.*.

76. On January 15, 2014, Dormire testified that on January 14, 2014, he had obtained the pentobarbital that was intended to be used to execute Herbert Smulls. *See* Dormire Tr. 125:4-125:6.

77. DOC executed Mr. Smulls on January 29, 2014, fifteen days after DOC obtained the compounded pharmaceutical product from Defendant.

78. Upon information and belief, DOC stored the pentobarbital used to execute Mr. Smulls for fifteen days at room temperature before using it to execute Mr. Smulls.

79. Dr. Sasich has concluded that DOC's storing the pharmacy-compounded sodium pentobarbital at room temperature as directed by Defendant for fifteen days represented a "very troubling deviation from USP standards," and it create[d] a "very high risk that the compounded drug [] degrade[d] before it was used for Mr. Smulls execution," exposing Mr. Smulls to increased risk of excessive growth of bacterial contamination or the production of endotoxins within the drug. *Id.* ¶ 55.

80. Improper storage of pentobarbital can result in contamination by bacterial growth or the production of endotoxins in the compounded drug. *Id.*

81. Dr. Sasich opined that the compounding pharmacy's "failure to adhere to nationally recognized and widely accepted standards also suggests that it may lack the equipment, facility, knowledge, or expertise to properly compound sterile pentobarbital sodium injections." *Id.* ¶ 57.

82. In particular, Dr. Sasich found the failure of the pharmacy to instruct the Department of Corrections on proper storage of the drug to be "deeply troubling." *Id.* ¶ 57.

83. Improper storage creates "a very substantial, even grave, risk that the prisoner will suffer severe pain and/or an immediate severe allergic reaction." *Id.* ¶ 56.

e. The lack of regulation, unreliability of the product, ineffective testing, and incorrect instructions are likely to cause grave pain and suffering.

84. When used as the lethal ingredient in a lethal injection , Defendant's unregulated pharmacy-compounded pentobarbital is likely to cause serious, unnecessary, lingering, and ultimately inhumane pain and suffering for several reasons including:

(a) Lack of identity as to the product the label represents the substance to be;

(b) "[S]ub-poten[cy]" and super-poten[cy]," resulting in unanticipated effects such as pulmonary embolism, nausea and vomiting, suffocation and gasping for breath before the hoped-for loss of consciousness, and partial or complete lack of effect;

(c) Contamination with dangerous allergens or substances capable of causing immediate anaphylactic reactions;

(d) Contamination with bacteria or fungus with immediate excruciating effects, such as "[h]ighly unpredictable, rapidly evolving, and potentially painful and agonizing reactions" before the condemned person is unconscious (assuming it works even to that extent);

(e) Incorrect pH (acidity level) resulting in serious pain from the burning sensation on injection analogous to the effect of injecting an unanesthetized condemned person with potassium chloride; and, without limitation,

(f) Formation of precipitates, i.e., solid particles, with the foreseeable result of a painful pulmonary embolism in the most serious of cases.

Sasich Affidavit ¶¶ 23-32.

85. The circumstances surrounding the execution of nonparty Dennis B. McGuire illustrate in vivid detail the risks associated with using compounded drugs as lethal ingredients in lethal injections.[3]

(a) Dennis B. McGuire was executed by the state of Ohio on January 16, 2014.

(b) Ohio's execution protocol calls for the use of a compound intravenous injection of midazolam and hydromorphone in the event that no pentobarbital is available.

(c) Ohio's execution protocol does not account for individualized characteristics of the individual to be executed, including body mass index.

(d) For the purposes of Mr. McGuire's execution, Ohio determined that no pentobarbital was available and instead, upon information and belief, purchased compounded midazolam and hydromorphone from a compounding pharmacy.

(e) Upon information and belief, Dennis McGuire's execution involved prolonged suffering, as demonstrated by his repeated episodes of writhing, clenching, and arching, and his audible gurgling, gasping, choking, grunting, and snorting. Upon information

[3]The facts herein alleged are based on the complaint in the matter captioned *Dennis R. McGuire, Individually and as Administrator of the Estate of Dennis B. McGuire v. Gary Mohr, et al.*, No. 14-CV-0093, before the United States District Court for the Southern District of Ohio.

and belief, these episodes demonstrate that during the *approximately nineteen minutes* following the injection of the compounded midazolam and hydromorphone but prior to his expiring, Mr. McGuire experienced frequent episodes of air hunger and suffocation. Upon information and belief, Mr. McGuire was conscious during the majority of this time.

(f) At a certain point, Dennis McGuire finally stopped experiencing these episodes, but a member of the execution team who examined him could not pronounce him deceased for another approximately five minutes.

86. Mr. McGuire's unnecessary pain and suffering were consistent with the predictions offered by his medical expert in support of a stay of execution; they are also consistent with Dr. Sasich's predictions as to the risks associated with the use of compounded pentobarbital in lethal injections.

87. Similarly, Michael Lee Wilson, who was executed in Oklahoma with pentobarbital, cried out during his execution, "I feel my whole body burning!" *See* Hancock, *Execution Secrecy*, *supra*. This sensation is consistent with receipt of contaminated pentobarbital. *See* Sasich Decl. ¶¶ 60-61.

88. And Eric Robert, an inmate executed in South Dakota by use of compounded pentobarbital, appeared to clear his throat, gasp heavily, and snore, his skin turned a blue-purplish hue, he opened his eyes and they remained open until his death, and his heart continued to beat for ten minutes after he stopped breathing. *Id.* ¶ 62. It took the state twenty minutes to declare him dead. *Id.* This reaction is consistent with use of either contaminated or sub-potent drug. *Id.* ¶ 63.

IV. By compounding and selling pentobarbital, a copy of a commercially available FDA-approved drug, Defendant has introduced or delivered for introduction into interstate commerce an adulterated and/or misbranded drug in violation of the Food, Drug, and Cosmetic Act.

89. Congress enacted the Federal Food, Drug, and Cosmetic Act (the "FDCA") in 1938 to "prohibit the movement in interstate commerce of adulterated and misbranded . . . drugs . . . ." Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 *et seq.*). The goal of the FDCA, as amended by the FDA Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (the "FDAMA") and the Compounding Quality Act, Pub. L. No. 113-54, 127 Stat. 587 (2013) ("CQA") is "to protect the public from exposure to . . . harmful drugs." Margaret A. Hamburg, *New Law Enhances Safety of Compounded Drugs and Protection of the Drug Supply Chain*, FDA Voice (Dec. 2, 2013), *available at* http://blogs.fda.gov/fdavoice/index.php/tag/federal-food-drug-and-cosmetic-act/. The FDCA prohibits the "introduction or delivery for introduction into interstate commerce any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). The FDCA prohibits the "introduc[tion] or deliver[y] for introduction into interstate commerce any new drug" that lacks approval by the FDA, 21 U.S.C. § 355(a), or "any . . . drug . . . that is adulterated or misbranded," 21 U.S.C. § 331(a). The FDCA further prohibits the "adulteration or misbranding of any . . . drug . . . in interstate commerce." 21 U.S.C. § 331(b).

90. The FDCA defines a "new drug" as "[a]ny drug . . . not generally recognized . . . as safe . . . for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). Under the FDCA, a manufacturer must obtain FDA approval before it may introduce any "new drug" into interstate commerce, 21 U.S.C. §§ 331(d), 355(a); to obtain approval, the FDA requires manufacturers to submit application materials containing data that demonstrate that the new drug is both safe and effective for its intended uses and that it will be manufactured such that the drug will preserve its identity, strength, quality, and purity, 21 U.S.C. § 355(a)-(d).

91. A drug is "adulterated" under the FDCA if

> the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with good manufacturing practice to assure that such drug meets current [FDCA safety requirements] and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

21 U.S.C. § 351(a)(2)(B).

92. A drug is "misbranded" under the FDCA "[u]nless its labeling bears . . . adequate directions for use." 21 U.S.C. § 352(f)(1).

93. The Compounding Quality Act of 2013 ("CQA") exempts compounded drugs from certain restrictions pertaining to misbranding of drugs contained in 21 U.S.C. § 352(f)(1), if the drug is "compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility" under 21 U.S.C. § 353a-b. An "outsourcing facility" is a facility at one geographic location or address that compounds sterile drugs, complies with all of the requirements of 21 U.S.C. § 353b, and has registered with the U.S. Secretary of Health and Human Services as an outsourcing facility. 21 U.S.C. § 353b(d)(4).

94. As of January 31, 2014, Defendant had not registered with the U.S. Secretary of Health and Human Services as an outsourcing facility under 21 U.S.C. § 353b. *See* U.S. Food & Drug Admin., Registered Outsourcing Facilities (Jan. 31, 2014), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm.

95. The FDAMA exempts some compounded drugs from the statutory restrictions pertaining to adulteration and misbranding of drugs codified at 21 U.S.C. §§ 351(a)(2)(B) and 352(f)(1). The FDAMA nonetheless prohibits introduction, or delivery for introduction, into interstate commerce of a compounded drug unless the following necessary conditions are met:

(a) "the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient," 21 U.S.C. § 353a(a); and

(b) "the licensed pharmacist . . . does not compound regularly or in inordinate amounts (as defined by the Secretary [of Health and Human Services]) any drug products that are essentially copies of a commercially available drug product," 21 U.S.C. § 353a(b)(1)(D).

96. Pentobarbital is manufactured by the Danish pharmaceutical company Lundbeck and marketed for sale in the United States under the trade name Nembutal.

97. Since on or about October 2013, DOC has submitted to Defendant at least three prescriptions for compounded pentobarbital. Defendant has compounded pentobarbital and issued it to DOC in fulfillment of each prescription submitted to Defendant by DOC.

98. Defendant's compounding of pentobarbital constitutes regular compounding of a drug product that is essentially a copy of Nembutal, a commercially available drug product.

99. By compounding pentobarbital, Defendant has "introduce[d] or deliver[ed] for introduction into interstate commerce [] a[] . . . drug . . . that is adulterated or misbranded," in violation of 21 U.S.C. § 331(a).

V. Defendant provides compounded pentobarbital to DOC without regard for the medical history, issues, or needs of the individuals for whom the pharmaceutical product is prescribed.

100. Upon information and belief, Defendant required and requires DOC to provide a prescription for the compounded pentobarbital in the name of each individual to be executed.

101. Defendant knows or should know that DOC has used and uses the services of a single prescribing doctor, who is a member of DOC's execution team, to write prescriptions for

compounded pentobarbital in the name of individuals to be executed, upon request by DOC. *See* Dormire Tr. 102:9-102:13.

102. Defendant knows or should know that the prescribing doctor writes prescriptions for pentobarbital in the name of condemned persons without consulting with or examining those individuals, and without examining their medical records. *See id.* at 102:14-102:23.

103. Pursuant to the terms of his or her contract with the DOC, the prescribing doctor must provide a prescription for pentobarbital on behalf of DOC in the name of the individual to be executed and has no discretion not to write the prescription. *See id.* at 104:19-105:8.

104. DOC pays the prescribing doctor $300 in cash for each prescription for compounded pentobarbital the doctor issues. *See id.* at 128:9-128:15.

105. Upon information and belief, the pharmacist who fills the prescription for the compounded pentobarbital at the request of DOC does so without regard to the specific medical history, issues, and needs of the individual to be executed.

CLAIMS FOR RELIEF

COUNT 1
CRUEL AND UNUSUAL PUNISHMENT

106. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

107. Defendant's improper and unregulated methods of compounding pentobarbital and its faulty instructions to DOC on the proper use and storage of the drug will cause needless suffering by Plaintiff, including but not limited to immediate anaphylactic reactions, excruciating effects due to bacterial or fungal contamination, and other effects that are inhumane and unnecessary to the contemplated purpose of execution.

108. Defendant's production and delivery of compounded pentobarbital to the DOC crates an unnecessary risk that Plaintiff will suffer harm because other drugs exist that may be used to execute inmates in a manner that is less painful and more humane than execution by compounded pentobarbital.

109. The compounded pentobarbital prepared and supplied by Defendant creates an objectively intolerable and constitutionally unacceptable risk of harm to Plaintiff.

110. Defendant works in concert with the DOC to execute individuals on death row, including Plaintiff. Missouri recognizes Defendant as a member of the execution team and as such, it provides Defendant with certain privileges and protections. Its role on the execution team and its joint activities with the DOC render Defendant a state actor.

111. As a state actor, Defendant is liable for the cruel and unusual punishment to be inflicted upon Plaintiff.

112. For the preceding reasons, the use of Defendant's compounded pentobarbital for Plaintiff's execution constitutes cruel and unusual punishment in violation of the Eighth Amendment of the U.S. Constitution, applied to the states by the Fourteenth Amendment and enforceable against Defendant as a state actor pursuant to 42 U.S.C. § 1983.

COUNT 2
PREEMPTION

113. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

114. Because Defendant works in concert with DOC to execute individuals and is, pursuant to DOC's execution protocol, recognized as a member of the execution team subject to certain privileges and protections, Defendant is a state actor for purposes of manufacturing and delivering compounded pentobarbital to DOC.

115. Defendant's delivery of compounded pentobarbital to DOC violates 21 U.S.C. § 331(a).

116. Defendant's delivery of compounded pentobarbital to DOC is incompatible with, and contrary to, congressional purposes and objectives as set forth in the FDCA, FDAMA, and CQA.

117. Defendant's unlawful delivery of pentobarbital to DOC, an act undertaken under the color of state law, is preempted under the Supremacy Clause. *See* U.S. Const. art. VI.

118. Plaintiff is entitled, under the Declaratory Judgment Act, to a finding that Defendant's unlawful delivery of pentobarbital to DOC is preempted under the Supremacy Clause.

COUNT 3
NEGLIGENCE PER SE

119. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

120. Defendant owes a duty of care to Plaintiff to comply with the requirements of the FDCA as amended which, among other things, make it unlawful to deliver compounded pentobarbital, an adulterated drug, into interstate commerce.

121. Defendant's fabrication and delivery of compounded pentobarbital to DOC violates 21 U.S.C. § 331(a).

122. As a direct and proximate cause of Defendant's production and delivery of unlawfully compounded pentobarbital to DOC, Plaintiff will suffer an increased risk of pain and inhumane treatment.

123. As a member of the American public, Plaintiff is a member of the class for whose benefit the FDCA, the FDAMA, and the CQA were enacted. The harm Plaintiff has suffered,

continues to suffer, and will suffer is the type of harm the FDCA, FDAMA, and CQA were designed to prevent, and Plaintiff is within the class of persons the FDCA, FDAMA, and CQA were intended to protect.

124. Accordingly, Defendant's issuance of compounded pentobarbital at all times has been and continues to be negligent as a matter of law.

COUNT 4
STRICT LIABILITY—FAILURE TO WARN

125. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

126. At all times relevant to this suit, Defendant engaged in the business of compounding and then placing into the stream of commerce pentobarbital for sale to, among others, DOC. It is DOC's official policy, pursuant to DOC's current execution protocol and common practice thereunder, to obtain the compounded pentobarbital directly from Defendant and, at all times, to maintain custody of the compounded pentobarbital until use in an execution.

127. At all times relevant to this suit, Defendant knew and knows that DOC and its agents and officials have been using, and continue to use, compounded pentobarbital to execute inmates sentenced to the death. Defendant knows, or has reason to know, that the use of compounded pentobarbital for executions carries substantial risks of causing unnecessary extreme and inhumane pain and suffering because of the compounded pentobarbital's impurity, nonsterility, contamination, adulteration, and/or subpotency. Defendant knows, or has reason to know, that these characteristics are a likely result of Defendant's use of counterfeit, untested, and/or unregulated ingredients, as well as improper manufacturing practices. Subpotency may prolong or fail to effectuate the execution; contamination with dangerous allergens or substances

may cause immediate anaphylactic reactions; and contamination with bacteria or fungus may cause immediate excruciating effects before the condemned person loses consciousness.

128. Defendant knows or should know that it is not possible to produce safe, effective, and pure sterile injections because non-sterile APIs are technologically too difficult to compound safely.

129. Upon information and belief, Defendant has not warned DOC or Plaintiff of these known, unique risks associated with the use of compounded pentobarbital for executions.

130. Defendant knows, or has reason to know, that each compounded pentobarbital solution is unique. Testing of previously compounded solutions does not bear on the purity, sterility, or potency of any other compounded pentobarbital solution.

131. Defendant knows or has reason to know that the laboratory it uses for testing is a party to over 200 lawsuits.

132. Defendant has violated its duty to label each dispensed syringe of compounded pentobarbital with precise, accurate instructions as to the proper storage, care, and use of compounded pentobarbital.

133. Defendant knows, or has reason to know, that the compounded pentobarbital must be stored at temperatures below the average room temperature and that compounded pentobarbital stored at room temperature for twenty-four hours or longer degrades rapidly and fosters bacterial growth, creating additional risks of pain and suffering for the condemned person.

134. Defendant has instructed DOC and its agents and officials that compounded pentobarbital may be stored at room temperature conditions and that compounded pentobarbital so stored does not expire until thirty days after the compounding process.

DOC has heeded these instructions and stores and will continue to store compounded pentobarbital at room temperature, often for two weeks or more. Defendant compounds each pentobarbital solution without regard to the specific medical history, issues, and needs of the individual to be executed. The pharmacist who provides the prescription for the compounded pentobarbital does so without regard to the specific medical history, issues, and needs of the individual to be executed. Beyond labeling, Defendant has violated its duty to provide additional direct written and oral instructions as to storage, care, and use of the compounded pentobarbital.

135. Defendant has violated its duty to inform DOC that its delivery of compounded pentobarbital is unlawful under the FDCA.

136. Defendant knows that it is unlawful to deliver drugs, such as compounded pentobarbital, that are adulterated or misbranded under the FDCA.

137. Defendant has not informed DOC or Plaintiff that its delivery of compounded pentobarbital is unlawful under the FDCA.

138. Defendant's failure to provide these and other warnings and instructions in conjunction with its issuance of compounded pentobarbital to DOC for use in Plaintiff's execution will proximately and directly cause pain, suffering, and injuries to Plaintiff. Upon information and belief, DOC, if properly warned of the risks of unregulated compounded pentobarbital, would not use Defendant's compounded pentobarbital for executions. Upon information and belief, DOC, if properly warned that Defendant's delivery of compounded pentobarbital is unlawful, would not use Defendant's compounded pentobarbital for executions. Upon information and belief, DOC, if appropriately instructed on the proper storage, handling, care, and use of the compounded pentobarbital, would heed those directions.

139. For the preceding reasons, Defendant's conduct was reckless, malicious, willful, or intentional, and Plaintiff is entitled to, among other forms of relief, compensatory and punitive damages.

COUNT 5
STRICT LIABILITY—DESIGN/MANUFACTURING DEFECT

140. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

141. Defendant is a pharmacy that compounds a product it identifies as pentobarbital. Defendant delivers compounded pentobarbital into the stream of commerce and expects the compounded pentobarbital to reach, among others, DOC for use in Plaintiff's execution.

142. The compounded pentobarbital manufactured and supplied by Defendant is defective in design and manufacture. Upon information and belief, Defendant's ingredients and compounding methods will produce a product that lacks necessary guarantees of purity, sterility, noncontamination, nonadulteration, and potency. These defects will exist in the compounded pentobarbital at the time the solution leaves Defendant's possession.

143. These defects render the compounded pentobarbital unreasonably dangerous to those receiving the drugs, including Plaintiff and other similarly situated condemned persons. The compounded pentobarbital creates the risk that a condemned person, such as Plaintiff, will experience immediate anaphylactic reactions, excruciating effects due to bacterial or fungal contamination, and other effects that are inhumane and unnecessary to the contemplated purpose of execution.

144. The compounded pentobarbital will be the direct cause of Plaintiff's unnecessary and inhumane pain and suffering.

145. Other drugs exist that may be used to execute inmates in a manner that is less painful and more humane than execution by compounded pentobarbital.

146. For the preceding reasons, Defendant's conduct is reckless, malicious, willful, or intentional, and Plaintiff is entitled to, among other forms of relief, compensatory and punitive damages.

COUNT 6
NEGLIGENCE

147. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

148. Defendant owes a duty to exercise reasonable care in the design, study, manufacture, compounding, and labeling/instructions of its pentobarbital.

149. Defendant owes this duty of care to the intended recipients of the drugs it produces, including Plaintiff.

150. Defendant breached its duty of care in the design and manufacture of the compounded pentobarbital by, among other things—

(a) failing to conduct studies, tests, and evaluations of the identity, potency, purity, and contamination of the chemical ingredients it uses to compound pentobarbital;

(b) failing to conduct studies, tests, and evaluations of the finished dosage of compounded pentobarbital;

(c) failing to trace the raw chemicals used in compounding to the original manufacturers for information on quality, packaging, storage, shipment conditions, and chains of custody;

(d) using ingredients produced in non-FDA registered, non-FDA inspected facilities, or by using ingredients without verifying that they were produced in FDA-registered, FDA-inspected facilities;

(e) using unregulated and/or imported, substandard ingredients, including adulterated or counterfeit chemicals;

(f) failing to follow the FDA's Good Manufacturing Practices in compounding pentobarbital.

151. Defendant knows or has a reasonable basis for knowing that safe, effective, and pure sterile injections cannot be produced by compounded pharmacies because sterile injectable drugs that start with sterile APIs are technologically too difficult to compound safely.

152. Defendant is breaching its duty of care by failing to provide adequate warnings to DOC and Plaintiff as to the risk of compounded pentobarbital, by failing to provide DOC and Plaintiff with precise, specific instructions as to the storage, care, and use of pentobarbital, and by failing to inform DOC and Plaintiff that its delivery of compounded pentobarbital is unlawful under the FDCA.

153. Defendant breached its duty of care by compounding pentobarbital for Plaintiff according to a prescription issued without regard to Plaintiff's medical history, issues, and needs.

154. Defendant's conduct as described above will be the direct cause of Plaintiff's unnecessary and inhumane pain and suffering.

155. Defendant's failures to conduct relevant tests, failure to trace ingredients, failure to use ingredients only from FDA-registered and/or -inspected facilities (or to verify that its ingredients come only from FDA-registered and/or –inspected facilities), use of substandard ingredients, and failure to comply with the FDA's Good Manufacturing Practices create a

substantial risk that the compounded pentobarbital will cause Plaintiff unnecessary and inhumane pain and suffering.

156. DOC, if warned of the risks of unregulated compounded pentobarbital, would not use Defendant's compounded pentobarbital for executions. DOC, if instructed on the proper storage, handling, care, and use of the compounded pentobarbital, would heed those directions. DOC, if informed that delivery of Defendant's compounded pentobarbital is unlawful, would not use Defendant's compounded pentobarbital for executions.

157. Defendant's conduct as described above has substantially diminished Mr. Taylor's chances of experiencing the appropriate medical outcome—viz., a humane and efficacious execution that affords basic respect and dignity to Mr. Taylor.

158. For the preceding reasons, Defendant's conduct is reckless, malicious, willful, or intentional, and Plaintiff is entitled to, among other forms of relief, compensatory and punitive damages.

COUNT 7
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

159. Plaintiff incorporates by reference each and every statement and allegation set forth above as if fully restated herein.

160. Defendant is intentionally supplying compounded pentobarbital to be used in the execution of inmates in Missouri, including Plaintiff.

161. Defendant supplies the compounded pentobarbital with knowledge that it is prepared and supplied in a manner that fails to ensure the drug's sterility, identity, purity, potency, and efficacy.

162. Defendant's methods of preparing and supplying pentobarbital for the execution of the condemned in Missouri, including Plaintiff, are extreme and outrageous because they

circumvent or disregard the safeguards that would ensure the sterility, identity, purity, potency, and efficacy of the drug.

163. Plaintiff is aware that that Defendant prepares compounded pentobarbital, including that which will be used for his execution, in a manner that fails to ensure its safety, purity and efficacy. As a result of this knowledge, Plaintiff suffers extreme distress, anxiety, and fear as he legitimately worries that the last moments of his life will be consumed by severe and unnecessary pain and suffering.

164. Plaintiff fears that his family will also suffer severe distress when they witness or learn that his execution occurred in a manner that caused him unnecessary, inhumane, and torturous suffering.

165. For the preceding reasons, Defendant's conduct constitutes the intentional infliction of emotional distress upon Plaintiff under Oklahoma law.

PRAYER FOR RELIEF

166. WHEREFORE, Plaintiff, Michael A. Taylor, requests the following relief against the Defendant:

(a) A declaratory judgment that Defendant's delivery of compounded pentobarbital to the DOC for use in the execution of condemned persons, including Michael Taylor, (i) constitutes cruel and unusual punishment in violation of the Eighth and Fourteenth Amendments; (ii) is negligent or otherwise unlawful and/or illegal; (iii) is preempted by federal law; or (iv) gives rise to liability to Michael Taylor, based on Defendant's failure to provide adequate warnings and instructions, manufacture and design of a unreasonably dangerous product, and outrageous and intentional conduct directed at Michael Taylor;

(b) An order temporarily restraining and preliminarily enjoining Defendant from delivering compounded pentobarbital to the DOC for use in the execution by lethal injection of Michael Taylor;

(c) An order permanently enjoining Defendant from delivering compounded pentobarbital to the DOC for use in the execution by lethal injection of Michael Taylor or another condemned person scheduled for execution by lethal injection;

(d) Compensatory damages in excess of the jurisdictional amount, including, but not limited to, non-economic damages in excess of $75,000;

(e) Damages for pain and suffering;

(f) Reasonable attorney's fees as well as the costs of suit; and

(g) Such further relief as this Court deems necessary, just and proper.

RESPECTFULLY SUBMITTED,

/s/ Paul DeMuro

Paul DeMuro, OBA No. 17605
FREDERIC DORWART, LAWYERS
124 E. 4th Street
Tulsa, Oklahoma 74103
(918) 583-9922 – Telephone
(918) 583-8251 – Facsimile
Email: pdemuro@fdlaw.com

and

Matthew S. Hellman
(*pro hac vice* application forthcoming)
Carrie F. Apfel
(*pro hac vice* application forthcoming)
JENNER & BLOCK, LLP
1099 New York Avenue NW, Suite 900
Washington, DC 20001-4412
(202) 639-6861 – Telephone
(202) 661-4983 – Facsimile
Email: MHellman@jenner.com
CApfel@jenner.com

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID ZINK, et al.,)
)
Plaintiffs,)
) No. 2:12-CV-4209-BP
vs.)
)
GEORGE A. LOMBARDI, et al.,)
)
Defendants.)

DEPOSITION OF DAVE DORMIRE
Taken on behalf of the Plaintiffs
January 15, 2014
Julie K. Kearns, CCR 993

Zink v. Lombardi, No. 2:12-CV-4209-BP
U.S. Dist. Ct. W.D. Mo.
Amended Complaint
Exhibit 41

INDEX OF EXHIBITS

(Whereupon the exhibits 1, 2, 5, 6 and 7 were attached to the original and copies. Exhibits 8 and 9 retained by counsel.)

Zink v. Lombardi, No. 2:12-CV-4209-BP
U.S. Dist. Ct. W.D. Mo.
Amended Complaint
Exhibit 41

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID ZINK, et al.,)
)
Plaintiffs,)
) No. 2:12-CV-4209-BP
vs.)
)
GEORGE A. LOMBARDI, et al.,)
)
Defendants.)

DEPOSITION OF DAVE DORMIRE, produced, sworn, and examined on the 15th day of January, 2014, between the hours of one o'clock in the afternoon and seven o'clock in the evening of that day, at Missouri Department of Corrections, 2729 Plaza Drive, Jefferson City, Missouri, before Julie K. Kearns, a Certified Court Reporter within and for the State of Missouri, in a certain cause now pending before the Circuit Court of the County of St. Louis in the State of Missouri, wherein DAVID ZINK, et al. is the Plaintiff, and GEORGE A. LOMBARDI, et al. is the Defendant.

Zink v. Lombardi, No. 2:12-CV-4209-BP
U.S. Dist. Ct. W.D. Mo.
Amended Complaint
Exhibit 41

A P P E A R A N C E S

For the Plaintiffs:
Elizabeth Unger Carlyle, Esq.
ELIZABETH CARLYLE LAW OFFICE
6011 OAK STREET
Kansas City, Missouri 64113

For the Defendants:
David Hansen, Esq.
Michael Spillane, Esq.
Susan Boresi, Esq.
MISSOURI ATTORNEY GENERAL'S OFFICE
211 West High Street
Jefferson City, Missouri 65102

The Court Reporter:
Ms. Julie K. Kearns
Midwest Litigation Services
3432 West Truman Boulevard, Suite 207
Jefferson City, Missouri 65109
(573)636-7551

Zink v. Lombardi, No. 2:12-CV-4209-BP
U.S. Dist. Ct. W.D. Mo.
Amended Complaint
Exhibit 41

[redacted] [redacted]

[redacted].

A. [redacted].

Q. (By Ms. Carlyle) Well, do you have knowledge of it -- have you heard something about it?

A. I --

MR. HANSEN: I'm going to object to this question because it could potentially reveal the identity of the pharmacy, so --

MS. CARLYLE: Well, I mean, I suppose if that's true, anything could. I mean, I could ask him -- you know, I could -- you know, knowing whether -- there are presumably any number of pharmacies that have supplied prisons.

MR. HANSEN: You can get that information from other sources or from them, but you can't get it through this witness.

MS. CARLYLE: Okay. So you're directing him not to answer the question has the pharmacy provided execution drugs for other prisons.

MR. HANSEN: He's told you he personally doesn't know. Beyond that, I'm going to direct him not to answer that question.

MS. CARLYLE: Okay.

MR. HANSEN: And I will note that we have

listed, correct?

A. Yes.

Q. Two of them say that the Pentobarbital was not available, correct?

A. Correct.

Q. And the third one provides a price of $8,000?

A. Yes.

Q. Was that the only bid you got for Pentobarbital?

A. Yes.

Q. Was there -- is there any requirement that you have more than one bid before making such a purchase?

A. We have to make contact with three potential sellers.

Q. But you don't have to obtain more than one actual quote?

A. No.

Q. Okay. Once you obtained this bid, did anyone attempt to negotiate about price or anything else with that pharmacy?

A. I did not.

Q. Did anyone else?

A. I don't know that anyone else did.

Q. Okay. Let me ask you to pull up page 12 -- or get in front of you page 1263. While -- actually, there are three pages I'd like for you to look at because I

you're asking the question, but it is --

Q. (By Ms. Carlyle) Well, let me explain. There are -- I am asking you whether it falls into one of two categories. One would be a Missouri pharmacy. The other would be a pharmacy somewhere else that had been licensed by Missouri to allow it to sell drugs in Missouri.

MR. HANSEN: Again, I object to the form of the question and lack of foundation.

A. I do not know the answer to that question.

Q. (By Ms. Carlyle) Okay. Did anyone at the Department of Corrections make inquiry about whether any professional complaints had been filed against the pharmacy that supplies the Pentobarbital?

A. Again, I do not know the research Mr. Briesacher did.

Q. Okay. Do you think that if anyone did, it would have been Mr. Briesacher?

A. Yes.

Q. Okay. Let me ask you to take a look at page 1260, again, of Exhibit 1, the disk with the discovery supplied in January 2014.

A. 1260?

Q. 1260.

A. Okay.

Q. Can you tell us what that is, please.

A. That is a memo from myself to the pharmacy indicating that they are to be known as pseudonym M6.

Q. Okay. You say they are to be known. Is it the entity or a particular individual who is M6?

A. I addressed this to an individual.

Q. So is there a separate pseudonym for the concern that the individual works for?

A. No.

Q. So you addressed it to an individual. What sort of individual is he or she? What kind of job does that individual do?

MR. HANSEN: Objection, form of the question in that it lacks foundation.

MS. CARLYLE: I mean, what I'm looking for is something like a pharmacist, the head of the company, the secretary, the clerk, you know. I'm not looking for the name of an individual, I'm just looking for a function of the person to whom you assigned that M6 designation.

MR. HANSEN: I'm objecting to the form of the question. It lacks foundation. I think the question should be do you know and then he can say yes or no.

MS. CARLYLE: Okay.

MR. HANSEN: I'm objecting to the form of the question because it lacks foundation.

MS. CARLYLE: Okay. Well, Mr. Hansen, do you

A. The first one is -- I would describe as permits, retail pharmacy. The second one is a certification of registration. The third one is a controlled substance registration certificate.

Q. Okay. And did they all pertain to the same business?

A. Pardon?

Q. Do they all pertain to the same business?

A. Yes.

Q. Because as a result of redactions, we can't tell what business they pertain to, correct?

A. Yes; yes.

Q. Okay. Will you tell us what state the pharmacy is licensed in?

MR. HANSEN: I'm going to object to that question, it would be information that would lead to the identity of the pharmacy, and I'll instruct him not to answer that question.

Q. (By Ms. Carlyle) Okay. Just so it will be on the record, the St. Louis public radio has reported that the pharmacy is licensed in Oklahoma. Are you willing to confirm or deny that?

MR. HANSEN: Same objection, same instruction.

Q. (By Ms. Carlyle) Is the expiration date of the license redacted in this -- ~~this iteration of this~~

document? In this document on page 1261.

A. Yes.

Q. Okay. Why was that redacted?

A. I believe it was redacted because of attempts to identify the pharmacy.

MS. CARLYLE: Could you mark this as Exhibit 5, please?

(Exhibit No. 5 marked for identification.)

MS. CARLYLE: I'll show you what I've got because I don't have another copy.

MR. HANSEN: Okay. I'll just clarify. I saw it was identified as amended complaint, but this is an exhibit that was a page from the complaint.

MS. CARLYLE: It was attached to the complaint, yes. I think it reflects actually on its -- at the bottom of it.

MR. HANSEN: Yes, I see that.

MS. CARLYLE: But let me just say that it is the -- it is page eight of Exhibit 13 to the amended complaint filed in this case, I believe on December 3. And I believe that's actually -- the filing date is actually reflected on that document.

MR. HANSEN: I'm not sure -- are you going to ask him many questions about it or just briefly? Because I'm going to want a copy of it. I don't have that handy

MS. CARLYLE: Okay.

A. The names appear -- as far as state witness, they appear to be the same, as far as the names.

Q. (By Ms. Carlyle) I see. And let's take a look at 2043. Okay. What -- that's a photograph. What's it a photograph of?

A. It's a photograph of four syringes.

Q. Okay. Can you tell me the nature of the information that's redacted on those syringes?

A. It would be the name of the pharmacy.

Q. Okay. Can you tell me what -- can you just tell me what 2015 is, what it's for?

MR. HANSEN: Which page?

MS. CARLYLE: 2015.

MR. HANSEN: It would have been a lot easier if you went to chronological order.

MS. CARLYLE: I know.

A. It is a count report.

Q. (By Ms. Carlyle) 2015?

A. What?

Q. 2015.

A. I'm sorry.

Q. That's okay. I was going to say wait a minute.

A. 20 -- I'm sorry.

Q. That's okay. There are a lot of notes.

object.

MS. CARLYLE: And direct him not to answer.

MR. HANSEN: Direct him not to answer. He certainly can tell you whether or not he knows the answer to that question, but I'm going to direct him not to answer the question.

A. I have seen the license, but I do not know the date.

Q. (By Ms. Carlyle) Okay. Did the person who prescribed the -- first of all, was it the same person who prescribed the Pentobarbital for both Mr. Franklin and Mr. Nicklasson?

A. Yes.

Q. Did that person examine Mr. Franklin or Mr. Nicklasson before he wrote the prescription?

MR. HANSEN: Objection to the form of the question because it lacks foundation.

A. No.

Q. (By Ms. Carlyle) No, he didn't?

A. No.

Q. Did he examine Mr. Franklin or Mr. Nicklasson's medical records before writing the prescription?

A. No.

Q. There are a bunch of copies of the prescriptions, but let's take a look at 1254. And is the

for a legal conclusion and an expert opinion. Answer to the degree you can.

A. It simply says contractor will provide the Department with the requested prescriptions.

Q. (By Ms. Carlyle) Okay. So in order to -- in order to fulfill his contract when he's requested to do so, he has to write the prescription?

A. That's what it says.

Q. Okay. How much Pentobarbital -- compounded Pentobarbital does the Department of Corrections have on hand at the moment?

A. Ten grams.

Q. And is that for Mr. Smulls' execution?

A. Yes.

Q. Is new Pentobarbital ordered for each execution?

A. Yes.

Q. If that -- and that Pentobarbital is scheduled to be used on January 29?

A. Yes.

Q. If Mr. Smulls -- if Mr. Smulls' execution doesn't occur, what would happen to that Pentobarbital?

A. It would be destroyed.

Q. You indicated in your interrogatory response that the pharmacy said to store the Pentobarbital at room temperature?

A. That's correct.

Q. Okay. First of all, to whom was that communication made?

A. To me.

Q. Okay. Was it in writing?

A. No. It was -- that was a verbal statement to me when I asked how to store it.

Q. Okay. Recognizing that you're not going to -- let me put it this way. Do you know who told you that?

A. Yes.

Q. Okay. I understand you're not going to tell me now, but if you were directed to -- if you were told that the identity were not privileged, you wouldn't say I don't know who told me that. You know.

A. Yes.

Q. You also said that you had been told that the Pentobarbital expires 30 days after compounding; is that correct?

A. Yes.

Q. Is there a writing that reflects that?

A. There's not a writing that I know of. It is in -- it is clearly reflected in the labels of the discard date and what -- it confirms what I've been told, that it is good for 30 days.

Q. Okay. But you -- were you also told that

verbally?

A. By Mr. Briesacher.

Q. Okay. You weren't told that by anyone at the pharmacy?

A. It's -- I believe the subject came up in conversations regarding the discard date and it was -- in our conversations, it was generally assumed that we had to -- I could not request the pharmacist to compound Pentobarbital over 30 days before an execution date.

Q. Okay. And do you know who you had that conversation with?

A. Yes.

Q. Okay. Has anyone explained to you why it lasts 30 days rather than some other length of time?

A. Not in great detail. I know bits and pieces, but not in great detail.

Q. What are the bits and pieces that you know?

A. Simply -- there's references to ensuring that it's sterile, there's things like that, that it's -- my understanding is that is a conservative estimate, that it is still an appropriately prepared substance well beyond that, but that's the day they picked to use by.

Q. Okay.

MR. HANSEN: Elizabeth, it is 5:15 and we've been going a pretty good chunk here.

Do you think that -- I mean, I guess let me ask you, would your responses about this one be the same as they were about the -- about 1266?

A. Yes.

Q. Okay. What about 1285? Is that an analysis of compounded Pentobarbital?

A. I believe so.

Q. Okay. Now, the redacted material at the top, would -- is that the name of the laboratory?

A. Yes, I believe so.

Q. Okay. Then the client is redacted and what -- you know, what's that? Is that the pharmacy or the prescriber or --

A. That would be my belief, that that's the pharmacy.

Q. So in this context, the laboratory sees its client as the pharmacy? It's performing --

MR. HANSEN: Objection --

Q. (By Ms. Carlyle) It's performing the analysis for the pharmacy.

MR. HANSEN: Object to the form of the question. This witness doesn't know what the pharmacy sees the lab as. It calls for speculation on the part of this witness.

MS. CARLYLE: Okay. I'm actually -- what I actually said was based on this document from the

here, but it's 6:05 P.M. now, just so we remember.

MS. CARLYLE: Okay.

(Off the record.)

Q. (By Ms. Carlyle) When did -- when did you get the Pentobarbital for Mr. Smulls' execution?

A. Yesterday.

Q. Okay. Let's take a look at some money things. 1295. Okay. 1295 -- 1296.

A. 1296.

Q. 1296, I'm sorry.

A. Okay.

Q. Okay. 1296 reflects a payment of $1,200 to -- for the Joseph Franklin execution; is that correct?

A. Yes.

Q. And are these documents used -- they're called Confidential Execution Team Member Receipt. Are those used to pay those members of the execution team whose identities the Department is protecting?

A. Yes.

Q. So the redacted material in the middle presumably identifies the person who got the payment?

A. Yes.

Q. So this person obtained -- got $1,200 and that was disbursed by Melissa Rohrbach?

A. Rohrbach is the pronunciation?

Q. And does Miss Rohrbach work at -- work in this office or does she work in ERDCC or --

A. She works in our finance office downstairs.

Q. Okay. So what was the job of the person who got $1,200? Is that M2, M3?

A. It's M2.

Q. That's M2. Okay. Turning to 1297.

A. Yes.

Q. I guess this is -- this is a -- a voucher for $3,000 for Joseph Franklin's execution. Who gets $3,000?

A. This is M3.

Q. That's M3. Okay. Let's switch. There's -- in -- let's look at 2058, I think. 2057?

MR. HANSEN: 2058, is that what --

MS. CARLYLE: Actually, 2057.

A. Okay.

Q. (By Ms. Carlyle) Okay. Who gets -- this is for the -- this is a payment of $11,091 for the execution of Allen Nicklasson. Who gets that?

A. That's the pharmacy.

Q. Okay. Now, the pharmacy's bid for the pentobarbital was $8,000, was it not?

A. That was correct.

Q. So what's the extra $3,091 for?

A. That was for testing.

Q. Okay. So the pharmacy collects the testing fee?

A. Yes.

Q. Okay. Let's look at 1300.

MS. CARLYLE: I promise by tomorrow I'll have these all on one thing and I won't have to do this.

MS. BORESI: You know M3 is going to be at a remote location tomorrow and we won't have a way to get documents to him.

MS. CARLYLE: Okay. He probably -- there probably aren't a whole lot of documents he's going to need, but that's an interesting issue. I think last time we got him some.

MS. BORESI: But you did it like a week in advance.

MS. CARLYLE: Yeah. If we'd have them a week in advance, it would have been easier.

Q. (By Ms. Carlyle) Okay. 1300 is what? What is 1300?

A. That's a -- the receipt at the pharmacy.

Q. Okay. And do we have -- and that's November 13; is that right? It's at the top.

A. Oh, yes; yes.

Q. I'm not trying to be tricky. Is that a receipt that -- well, let me just ask you this. I mean, how does the pharmacy get paid? Does it -- do you send them a

check or what happens?

A. I take them cash.

Q. You take them cash. Okay. Is that also true for M2 and M3?

A. Yes.

Q. Okay. And the -- so the $8,000 payment, the $11,000 payment were cash payments?

A. Yes.

Q. 1298. 1298 is a receipt for $300. Who gets $300?

A. M5.

Q. Okay. And M5 is?

A. The --

Q. Prescriber?

A. Prescriber.

Q. Okay. And who is Susan Wood?

A. Susan is in our finance office.

Q. Okay. And is that -- so is that also a cash payment?

A. Yes.

Q. Okay. What -- is there a -- is there an internal document that says that these people are to be paid in cash? How does that -- how does that happen? Who made the decision to pay them in cash, I guess is the question?

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Exhibit 41

Q. At the time this was --

A. Being considered, yes, yes.

Q. All right. And do you still -- do you still have those drugs in your inventory?

A. Yes.

Q. Are those drugs part of the protocol that has been adopted and is currently in use?

A. No.

Q. The only other question or topic I want to ask you about is back about 3:30 or so, you were asked some questions relating to M6 and M6 is the pseudonym for who or what?

A. It is -- on -- the contract is with the pharmacy.

Q. Okay. But that M6 refers to the pharmacy?

A. Yes.

Q. And you were --

A. Well --

Q. -- shown a document in response to Miss Carlyle's -- or along with Miss Carlyle's question which is found at page 12 of 60. And what is that document?

A. That is the naming of a pseudonym for team member of M6.

Q. That was the letter written to the pharmacy?

tell you how long.

Q. (By Ms. Carlyle) Do you think -- are you -- do you think it would be -- if you were to announce such a protocol now, that it would be appropriate to use that combination on Mr. Smulls on January 29?

A. It's awfully quick, but I don't make those final decisions.

Q. Is that a decision Mr. Lombardi makes?

A. Yes; yes.

Q. Okay. Let me just ask you a couple of things about this -- about M6. M6 you're now telling us is a pseudonym for the pharmacy as a whole?

A. We signed a -- we signed an agreement with the pharmacy that we would keep them confidential.

Q. Okay. Did you sign an agreement that you would keep the individual employees confidential?

A. Not with each individual employee, no.

Q. Okay. How many individual employees at the pharmacy have you dealt with?

A. Have I dealt with?

Q. Uh-huh.

A. Primarily one, but there is a second one that is somewhat involved.

Q. And are you willing to reveal their names?

A. No.

EXHIBIT 2

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

Michael Taylor, Plaintiff, v. The Apothecary Shoppe, Defendant.	CIVIL ACTION NO. _____ Complaint

DECLARATION OF LARRY D. SASICH

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this declaration are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. My background, experience and qualifications, in part, include:

a. Serving as a consultant to the Saudi Food and Drug Authority, Riyadh, Saudi Arabia;

b. Serving as Chairperson of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania, from 2007 to 2009;

c. Serving as a consultant to Public Citizen Health Research Group, Washington, D.C.; and

d. Serving as a Consumer Representative on the Science Board of Food and Drug Administration's, an advisory committee to the FDA Commissioner.

3. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology from the George Washington University, and a Doctorate of Pharmacy from University of the Pacific. I have completed a residency in nuclear pharmacy at the University of New Mexico. I have also been elected a Fellow in the American Society of Health-System Pharmacists (FASHP). I have also authored publications and/or presented analysis on drug safety issues. A complete list of my publications and presentations are listed in my Curriculum Vitae, which is appended to this Declaration as Exhibit A.

4. Counsel representing prisoner Michael A. Taylor, held by the Department of Corrections for the State of Missouri ("DOC") and currently scheduled for execution on February 26, 2014, have asked me to offer opinions on the substantial risks of pharmacy compounded drugs. Counsel also requested an overview of the pharmacy compounding industry in the United States and an opinion on the competency of contract testing laboratories used by compounding pharmacies to test their products.

5. Some jurisdictions require compliance with United States Pharmacopeial Convention (USP), Chapter <797> as the standard for compounding sterile products. The Oklahoma State Board of Pharmacy requires compliance with USP Chapter <797>.

Pharmacy Compounding in the United States

6. Traditional pharmacy compounding always involved altering a Food and Drug Administration ("FDA")-approved dosage form for a legitimate medical reason, according to a legal prescription for an individual patient, when that individual's needs

could not be met with an FDA-approved dosage. For example, altering a tablet or capsule to create an oral solution or suspension for patients who have difficulty in swallowing tablets or capsules would constitute traditional pharmacy compounding. The FDA generally exercises enforcement discretion over traditional pharmacy compounding and approves final finished dosage forms as safe, effective, and of acceptable quality for sale in the United States.

7. Non-traditional pharmacy compounding practice is more consistent with drug manufacturing. Unlike manufacturers, compounding pharmacies are generally not subject to the drug approval process and rigorous checks and regulatory procedures required under federal Good Manufacturing Practices (GMPs). They are subject to regulation, if at all by the states.

8. The non-traditional pharmacy compounding industry in which sterile products are produced from non-sterile Active Pharmaceutical Ingredients (APIs) emerged from the passage of the Food and Drug Administration Modernization Act (FDAMA) of 1997. Independent consumer and patient groups were opposed to the pharmacy compounding provisions of FDAMA, which they viewed as an end run around the FDA's drug approval process that would weaken public protections that have been evolving since the passage of the Pure Food and Drug Act of 1906.

9. These consumer and patient groups predicted a public health disaster from the passage of FDAMA. Their prediction was borne out with the 2012 nation wide epidemic of fungal meningitis that resulted in 64 deaths and over 700 cases of meningitis. This epidemic was the result of contaminated compounded injections produced by the New England Compounding Center of Framingham, Massachusetts.

10. In response to the New England Compounding Center disaster Congress passed and President Obama signed into law the Drug Quality and Security Act to close the safety gaps in the pharmacy compounding industry. This legislation requires compounding pharmacies to comply with the more stringent Good Manufacturing Practice (GMP) guidelines, rather than the more lax standard for compounded sterile products found in USP Chapter <797>.

The Risks of Pharmacy Compounded Drugs

11. The oversight of compounding pharmacies in the United States at this time is at best haphazard.

12. The production of injectable pentobarbital sodium, or other drugs, starting with a non-sterile Active Pharmaceutical Ingredient (API) is technologically too difficult to do outside of FDA-regulated facilities that must comply with federal GMP guidelines.

13. Non-traditional compounded drugs are not FDA-approved for any purpose. This means that the FDA has not verified their safety or effectiveness or the quality of their manufacture. As a result, the potential for product contamination in compounded drugs is far higher than that in manufactured drugs.

14. The Apothecary Shoppe is not an FDA-registered and inspected facility.

15. It is essential to use ingredients manufactured by FDA-registered and inspected manufacturers in order to ensure the quality of the final product. If poor quality ingredients are used, even the best compounding practices will not build quality and suitability into the final product.

16. The APIs used in compounding pharmacies may come from the grey market and be produced in non-FDA-registered, non-FDA inspected facilities. The ability

to trace raw APIs used in compounding back to the original manufacturers for information on quality, packaging, storage, shipment conditions and chains of custody from a chemical's cradle to grave is incredibly difficult.

17. APIs often come from plants in China or India, which may not be registered with or have records of inspection by the FDA. Plants in China have been identified in which pesticides are manufactured using the same equipment as is used to make APIs. By contrast, for an active ingredient to qualify for use in a finished dosage form, it must be manufactured in a US FDA-approved plant by a manufacturer holding a Drug Master File for the chemical.

18. Ethical chemical manufacturers who adhere to professional Responsible Care principles are unlikely to sell chemicals that may be used in grey market drug production operations (non-traditional pharmacy compounding or "manufacturing under the guise of pharmacy compounding"). Instead, they are more likely to sell directly to FDA-approved manufacturers of finished products. Accordingly, non-FDA registered chemical manufacturers are more likely to release large quantities of bulk chemicals into the grey market, increasing the likelihood that substandard chemicals will serve as the starting materials for both traditional and non-traditional compounding. Chemicals used in compounding are highly suspect, and there is no practical way to verify their quality, constitution or uniformity in limited pharmacy settings.

19. In this unregulated market, a chemical labeled to represent a certain active ingredient may actually contain another, quite different ingredient. Regulators and experts have identified the misidentification of chemicals as a significant problem among chemicals distributed in large quantities to pharmacies throughout the nation for use in

compounding.

20. Experts have concluded that compounded drugs, even those compounded in accordance with USP Chapter <797> have a low standard of sterility assurance compared to those manufactured in accordance with FDA-regulations. Compounding pharmacies generally do not assess the sterility of the their products, much less convey that information to prescribers or patients.

21. Compounding pharmacies generally do not have the ability to test chemicals for identity, potency, purity, and contamination. It is unlikely that The Apothecary Shoppe is capable of conducting testing to confirm the identity of a particular chemical, or to identify the presence of harmful contaminants that pose an immediate safety threat if administered intravenously.

22. Testing one lot of a chemical does not prove that a subsequent lot would have the same characteristics as the lot that was tested.

23. The use of non-sterile and potentially contaminated APIs creates a serious risk of harm, including reactions from bacterial, fungal and endotoxin contamination and contamination with allergens or substances that may cause immediate anaphylactic reactions. The presence of adulterants or growing organisms (like bacteria and fungus) may also accelerate chemical degradation resulting in a product that is sub-potent. The presence of growing organisms may also alter the final pH, with the potential of rendering the drug unstable or incompatible with human blood.

24. The use of unverified APIs further creates a serious risk of administering an entirely incorrect chemical or active ingredient.

25. A larger than expected moisture content of APIs risks inaccurate weighing

that may also result in a product that is sub-potent.

26. Both counterfeit or substandard ingredients and poor practice on the part of drug compounders often result in the production of pharmaceutical products that are contaminated or sub-potent and that lack the strength, quality, or purity represented on their labeling and required for the safe and effective treatment of patients. The potential harm associated with the use of such contaminated or sub-potent drugs is extremely high.

27. Several studies, including a survey conducted by FDA in 2001, have reported a high prevalence of quality problems with various pharmacy-compounded drugs, including sub-potency and contamination. The FDA conducted a follow-up survey of compounded drug products in 2006. The results showed that 33% of compounded drugs failed analytical testing using rigorously defensible testing methodology. Testing by the Missouri Board of Pharmacy, which is the only state which regularly tests compounded drugs, revealed that on average compounded drugs fail tests for potency and purity about 25% of the time, an extremely high failure rate. The FDA has observed similar failure rates for compounded drugs; observations during recent FDA inspections related to absent or limited sampling and testing of compounded drug products, for example, further support this failure.

28. Pharmacy compounded injectable pentobarbital sodium, or other compounded drugs, may contain endotoxins that can induce an inflammatory response manifested as a painful reaction, fever, and increased heart and respiratory rates that can cascade to organ failure and death. Contract-testing laboratories have failed to detect endotoxins in products they have tested.

29. A sub-potent dose of pentobarbital would result in less than effective

depression of the central nervous system.

30. In contrast, compounded drugs that are super-potent may result in a person experiencing suffocation and gasping for breath before loss of consciousness.

31. Compounded drugs contaminated by endotoxin, excessive growth of bacterial contamination, or the production of endotoxins or exotoxins will result in painful reactions. The use of a compounding pharmacy's product, as opposed to an FDA-compliant manufacturer's product, creates a substantial likelihood that the pH (acidity) of the solution injected will be incorrect. When the pH of the solution is incorrect, an individual will experience a burning sensation on injection analogous to the effect of injecting an unanethetized condemned person with potassium chloride. An analogous effect to be anticipated is the formation of precipitates, or solid particles of drug and other substances, with the foreseeable result of painful pulmonary embolism in the most serious cases

32. To use drugs from compounding pharmacies in the execution by lethal injection of a prisoner presents a substantial risk that the drugs will not work effectively for the announced purpose. Compounded pentobarbital may give rise to completely unanticipated responses including an allergic or anaphylactic reaction to an unidentified adulterant arising from intrinsic contamination of the ingredients or extrinsic contamination during the compounding procedure, or a pulmonary embolism arising from unanticipated drug incompatibilities, or partial or complete lack of effect due to ingredient tampering or controlled drug diversion after analytical testing—circumstances that would be expected to prolong the execution and multiply the pain and suffering beyond the objective of causing the condemned person's death. Highly unpredictable,

rapidly evolving, and potentially painful and agonizing reactions may ensue should the pentobarbital be contaminated by endotoxins or exotoxins. Similarly, should solid particulate matter of any kind contaminate the solution or precipitate out of solution during intravenous injection, there is a substantial risk of pain and suffering upon injection of the solution.

33. After-the-fact testing of compounded pharmaceutical products cannot alleviate these concerns. As former FDA Commissioner Jane Henney testified during a 2000 hearing before the House Energy and Commerce Committee, "no amount of finished product testing can build quality into the product."

34. Because there is inadequate oversight of both compounding pharmacies and the contract-testing laboratories used by compounding pharmacies the State of Oklahoma, DOC does not know with certainty what is contained in the pentobarbital sodium injection, or other compounded drugs, that will be injected into Mr. Taylor.

Contract Testing Laboratories

35. Pharmacy compounded pentobarbital sodium injections, or other injectibles, may not be sterile because contract-testing laboratories fail to follow proper testing procedures.

36. I have been informed that DOC has represented that at least one prior batch of pentobarbital sodium later used to execute a DOC prisoner was tested by a laboratory. It has been represented to me that the laboratory in question was Analytical Research Laboratories ("ARL") located in Oklahoma City, Oklahoma.

37. ARL is an example of a large contract-testing laboratory that has been linked to problems with pharmacy-compounded drugs. ARL was inspected by the FDA

from October 12, 2012 through November 8, 2012 and was cited for claiming to follow USP sterility and/or fungal testing standards when in fact it did not fully comply with the USP.

38. The failure of contract testing labs to follow widely accepted standards, such as those from the USP, has had negative national consequences. For instance, ARL reported favorable test results for pharmaceutical products compounded by New England Compounding Centers that recently produced the drugs that resulted in the deaths of 64 patients and sickened over 700 other patients.

39. The USP standards require a Method Suitability Test for all new products tested to insure that the product itself does not interfere with the sterility and/or fungal testing. The FDA inspection found that ARL did not have documentation to show that Method Suitability Tests had been performed for all products submitted to them by the New England Compounding Center. The FDA found that ARL had no documentation to show that all analytical methods used to test drug potency had been validated.

40. The FDA found ARL did not fully follow the USP test for endotoxins. ARL had 13 confirmed endotoxin failures for various drug products from October 2010 through October 2012. There is no documentation of any investigation into the causes of these endotoxin failures. Endotoxins induce an inflammatory response that is manifested as a painful reaction, fever, and increased heart and respiratory rates that can cascade to organ failure and death.

41. The Washington Post reported on October 5, 2013, in an article entitled, *"Labs that test safety of custom-made drugs fall under scrutiny,"* that five laboratories conduct testing for about 90 percent of the nation's large-scale compounding pharmacies.

These pharmacies produce drugs and other medical solutions for doctors, clinics and hospitals. The five laboratories were supposed to act as a safety net to ensure the sterility and potency of compounded drugs. However all five testing laboratories were cited by the FDA for not following USP quality standards. Some laboratories were not employing scientifically sound testing procedures and some laboratories failed to prevent contamination of the products tested. As a result, these laboratories could not reliably assess the strength, quality and purity of products they tested.

42. ARL represents on its website that it is accredited by the American Association for Laboratory Accreditation ("A2LA"). I am not aware of any drug regulatory authority (either the Food and Drug Administration or State Boards of Pharmacy) that recognizes accreditation by The American Association for Laboratory Accreditation. The probative value of A2LA's accreditation as to analytical testing of compounding-pharmacy products is unknown.

43. ARL has previously tested the pentobarbital compounded by The Apothecary Shoppe and used in a prior execution. However, the Certificate Of Analysis for pentobarbital sodium appears to come from an unknown commercial analytical laboratory and indicates a concentration of 50.490 mg/ml. A statement appears on this document that the method used in this determination was not validated. This is concerning because it erodes confidence in the reported concentration.

44. Furthermore, the documents ARL provided to DOC regarding the pharmaceutical product it tested leave critical questions unanswered. These questions include:

a. What is the source of the pentobarbital sodium active pharmaceutical

ingredient (API)?

b. Does this pentobarbital sodium API meet USP standards?

c. Was this pentobarbital sodium produced in an FDA-approved facility following Good Manufacturing Practice Guidelines?

d. Was the compounded pentobarbital sodium produced in a facility that would assure that cross-contamination would not occur with drugs that could cause potentially serious allergic reactions?

45. When ARL tested a pharmaceutical product used by DOC in at least one prior execution, ARL failed to test for adulterants, endotoxins, or sterility.

46. Before the Missouri execution of Herbert Smulls, the compounded execution drug was tested by ARL. The ARL Certificate of Analysis notes that an unknown residual solvent was found in the sample that was tested; yet the report indicated that the sample passed. It was later used to execute Mr. Smulls. It is unacceptable by any standard to inject an unknown substance into a human subject.

47. There are serious problems with contract testing laboratories that require one to question whether these companies are competent to determine if compounded drugs are safe, effective, and pure. The word testing carries weight that gives health professionals, the public, and policy makers a feeling of security if a product is tested. Great concerns arise if the testing is not reliable or valid.

Expiration Date and Beyond Use Date

48. Expiration dates are required on FDA-regulated drugs and are determined after extensive study of the final finished dosage form's stability. In contrast, the stability of compounded drugs is not known.

49. The Beyond Use Date (BUD) is defined by USP Chapter <797> as the date or time after which a compounded sterile preparation (CSP) shall not be administered, stored, or transported, and by USP Chapter <795> as the date after which a compounded preparation should not be used, determined from the date the drug is compounded. A compounded pharmaceutical product is not considered safe and effective after the expiration of the BUD.

50. USP Chapter <795> assigns BUDs for drugs compounded from non-sterile Active Pharmaceutical Ingredients (APIs). This is classified as High Risk compounding.

Beyond Use Dates for High Risk Compounding	
Room Temperature	Twenty-four hours
Refrigerated	Three days
Frozen at $\leq 10°$ C	Forty-five days

51. The BUD assigned in USP Chapter <795> apply only to compounded drugs prepared in accordance with USP Chapter <797>.

52. Key in determining a valid BUD for pharmacy-compounded pentobarbital sodium is knowing the expiration date for the pharmacy-compounded pentobarbital sodium product. Expiration dates are determined from the results of rigorous analytical and performance testing, and they are specific for a particular formulation in its container and at stated exposure to light and temperature. It should be recognized that the truly valid evidence for predicting a BUD can only be determined through product-specific experimental studies.

53. The stability of pharmacy-compounded drugs are unknown, therefore the

assigning of a scientifically supported valid BUD is both theoretically and practically impossible.

54. I have been informed that the pharmaceutical product compounded by The Apothecary Shoppe and used in the execution of Herbert Smulls was picked up from The Apothecary Shoppe and transported to DOC on January 14, 2014. It is my understanding that DOC was instructed by The Apothecary Shoppe to store the compounded pentobarbital at room temperature, and instructed that the compounded pentobarbital could be stored for up to thirty days. I have further been informed that Herbert Smulls was executed using pentobarbital compounded by The Apothecary Shoppe as the lethal ingredient on January 29, 2014. Thus the product used to execute Mr. Smulls was apparently stored at room temperature for a total of fifteen days.

55. The instruction by The Apothecary Shoppe to store the compounded pentobarbital at room temperature is a very troubling deviation from USP standards and creates a very high risk that the compounded drug would or did degrade before it was used for Mr. Smulls' execution. Among other risks, this improper storage could result in excessive growth of bacterial contamination or the production of endotoxins in the compounded drug.

56. The failure to properly store the pentobarbital intended for use in executions creates a very substantial, even grave, risk that the prisoner will suffer severe pain and/or an immediate severe allergic reaction.

57. The compounding pharmacy's failure to adhere to nationally recognized and widely accepted standards also suggest that it may lack the equipment, facility, knowledge, or expertise to properly compound sterile pentobarbital sodium injections.

The failure of the pharmacy to properly instruct the Department of Corrections on proper storage is deeply troubling.

58. Based on documents provided to me by counsel in *Zink v. Lombardi*, DOC obtained pentobarbital from the compounding pharmacy now identified as The Apothecary Shoppe on November 13, 2013. That pentobarbital was used in the execution of Joseph Franklin on November 21, 2013. The period of eight days during which the pentobarbital sat unused in the possession of DOC clearly falls outside the requirements of USP Chapter <797>, which states that high risk compounded drugs such as pentobarbital should not be used after one day if stored at room temperature, or three days if refrigerated.

59. Based on documents provided to me by counsel in *Zink v. Lombardi*, DOC obtained pentobarbital from the compounding pharmacy now identified as The Apothecary Shoppe on December 3, 2013. That pentobarbital was used to execute Allen Nicklasson on December 11, 2013, eight days later. The period of eight days during which the pentobarbital sat unused in the possession of DOC clearly falls outside the requirements of USP Chapter <797>, which states that high risk compounded drugs such as pentobarbital should not be used after one day if stored at room temperature, or three days if refrigerated.

Use of Compounded Drugs in Executions

60. On January 10, 2014, Oklahoma prisoner Michael Lee Wilson was executed under a three-drug protocol that used pentobarbital sodium injection produced by an unknown compounding pharmacy presumably located in Oklahoma. Time Magazine reported that within 20 seconds of receiving the injection Wilson cried that he

felt his "whole body burning."

61. It is my opinion that Mr. Wilson's reaction is consistent with contaminated pentobarbital sodium injection. Because of common problems with the safety procedures of compounded pharmacies and testing laboratories, and the lack of adequate oversight by federal and state authorities, the injection used in Mr. Wilson's execution could have contained cross-contaminates to which he was allergic, bacteria, or endotoxins. The injection could have had an altered pH due to contaminates. Additionally, because of this lack of oversight no one knows for sure what was injected into Mr. Wilson.

62. The South Dakota execution of Eric Robert used compounded pentobarbital. According to reports, Mr. Robert appeared to clear his throat, gasped heavily, and snored. Over a ten-minute period his skin turned a blue-purplish hue. During the course of his execution, he opened his eyes and they remained open until his death. It took 20 minutes for the state to declare Mr. Robert dead. Mr. Robert's heart continued to beat ten minutes after he stopped breathing.

63. It is my opinion that the events observed during Mr. Robert's execution are consistent with the administration of a compounded drug that was contaminated or sub-potent.

64. Safe, effective, and pure sterile injections cannot be produced outside of FDA regulated facilities that must adhere to agency GMPs and certainly cannot be produced in compounding pharmacies. Sterile injectable drugs starting with non-sterile APIs are simply technologically too difficult to compound safely.

65. An execution using compounded pentobarbital sodium, or other compounded drugs involves injecting a drug of unknown composition into a defendant.

This carries a substantial risk of causing the defendant pain and suffering.

I declare under pains and penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated this 11 day of February, 2014

Larry D. Sasich, PharmD, MPH, FASHP